Physically healthy voluntary pediatric patients aged 2 to 12 years old who were assigned to receive single oral cetirizine doses ranging from 5 to 60 mg. Food had no effect on the extent of cetirizine exposure (AUC) but reduced its peak plasma concentration (Cmax) by one-third.

Following oral administration of tablets or syrup in adults, cetirizine was rapidly absorbed. The mean time to reach the peak plasma concentration (Tmax) is 2 hours after a single dose. The mean oral dose of cetirizine hydrochloride was 3.4% lower than that observed in children with comparable age, indicating that the effect of food on the absorption of cetirizine is similar in both adult and pediatric patients.

Absorption

The mean plasma protein binding of cetirizine is 65%, independent of concentration. 

Clearance

The total body clearance in these elderly volunteers may be related to decreased renal function.

Excretion

Approximately 50% of the radioactivity was identified in the urine as the metabolite with negligible antihistaminic activity. The enzyme or enzymes responsible for this conversion are unknown. The metabolism of cetirizine has been extensively studied in animals and humans.

Metabolism

The mean plasma protein binding of cetirizine is 93%, independent of concentration.

Elimination

The safety and efficacy of QUZYTTIR for the treatment of acute urticaria was evaluated during a single, 5-mg oral cetirizine hydrochloride capsule, the mean Cmax was 275 ng/mL, and the elimination half-life was 63% shorter in this pediatric population compared to normal volunteers.

In children aged 2 to 12 years, the mean Cmax was 275 ng/mL, and the elimination half-life was prolonged by 50% and the apparent total body clearance was 40% lower in 16 geriatric subjects with a mean age of 77 years compared to normal volunteers. Patients on hemodialysis (n = 5) given a single, 10-mg dose of cetirizine hydrochloride (10 mg oral tablets once daily for 10 days), a mean peak plasma concentration (Cmax) of 311 ng/mL was observed and there was no hydrochloride (10 mg oral tablets once daily for 10 days), a mean peak plasma concentration (Cmax) of 311 ng/mL was observed and there was no

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**QUZYTTIR™**

**INDICATIONS AND USAGE**

QUZYTTIR™ is indicated for the treatment of acute urticaria. The recommended dosage for adults and children 12 years of age and older is 2 mL administered by intravenous injection. The recommended dosage for children 6 months of age and older, weighing 10 kg or more, is 2 mL administered by intravenous injection.

**DOSAGE AND ADMINISTRATION**

QUZYTTIR™ is for intravenous administration only. The recommended dosage for adults and children 12 years of age and older is 2 mL administered by intravenous injection over a period of 1 to 1.5 minutes. QUZYTTIR™ is not recommended in pediatric patients less than 6 months of age or in patients weighing less than 10 kg.

**PRECAUTIONS**

5.1 Somnolence/Sedation

The following adverse reactions associated with the use of oral cetirizine hydrochloride were identified in clinical trials.

- Sedation

Sedation was assessed by observation and/or self-report. Sedation was rated on a 0 to 3 scale (0 = none, to 3 = severe) with lower sedation scores indicating less sedation.

In a 35-day study of 72 adult volunteers, sedation was assessed in patients administered a single oral dose of 5, 10, or 20 mg of cetirizine hydrochloride. Sedation was assessed in a single group of 33 children who received cetirizine hydrochloride at the recommended dose of 2.5 mg administered by intravenous injection.

**ADVERSE REACTIONS**

The most common adverse reaction associated with the use of cetirizine hydrochloride was sedation. The incidence of sedation was approximately 42% in clinical trials of children and younger patients (6 months to 17 years of age) who received oral cetirizine hydrochloride and approximately 48% in clinical trials of adults (18 years and older) who received oral cetirizine hydrochloride.

- Nausea

The incidence of nausea was approximately 20% in clinical trials of children and younger patients (6 months to 17 years of age) who received oral cetirizine hydrochloride and approximately 28% in clinical trials of adults (18 years and older) who received oral cetirizine hydrochloride.

- Dizziness

The incidence of dizziness was approximately 10% in clinical trials of children and younger patients (6 months to 17 years of age) who received oral cetirizine hydrochloride and approximately 12% in clinical trials of adults (18 years and older) who received oral cetirizine hydrochloride.

- Headache

The incidence of headache was approximately 10% in clinical trials of children and younger patients (6 months to 17 years of age) who received oral cetirizine hydrochloride and approximately 12% in clinical trials of adults (18 years and older) who received oral cetirizine hydrochloride.

- Dry mouth

The incidence of dry mouth was approximately 10% in clinical trials of children and younger patients (6 months to 17 years of age) who received oral cetirizine hydrochloride and approximately 12% in clinical trials of adults (18 years and older) who received oral cetirizine hydrochloride.

**CLINICAL PHARMACOLOGY**

1.2 Mechanism of Action

Cetirizine hydrochloride is a white, crystalline powder that is water soluble. Cetirizine is a H1-receptor antagonist. The antihistaminic activity of cetirizine hydrochloride has been clearly documented in a variety of animal and human models. In the rat, it is the drug of choice for the prevention or treatment of the symptoms of allergic rhinitis and urticaria.

Cetirizine hydrochloride is a competitive, non-sedating antihistaminic that is a selective peripheral H1-receptor antagonist. Cetirizine hydrochloride is a competitive antagonist at the peripheral H1-receptors and possesses no measurable affinity for any other receptor known to be present in man. In vitro binding studies have shown no measurable affinity for receptors other than H1.

Cetirizine hydrochloride does not appear to have significant affinity for the muscarinic receptor or for alpha-1 receptors, nor does it have significant affinity for calcium channels or voltage-dependent sodium channels.

Cetirizine hydrochloride is exclusive of drug in animal milk does not necessarily predict the concentration of drug in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's health needs, the potential adverse effects on the breastfed child from the drug, and the importance of the mother's health needs. It is not known whether QUZYTTIR is excreted in human milk. The safety of QUZYTTIR in children 6 months to 17 years of age is supported by the safety data from the controlled clinical trials in this age group.

In one study, cetirizine hydrochloride oral tablets were given at doses up to 60 mg per day to pregnant women. In the first trimester of pregnancy, a study of 18 adult patients who received oral cetirizine hydrochloride at a dose of 10 mg/day over a period of 26 weeks found no adverse effect on pregnancy outcome. There was no evidence of any effect of oral cetirizine hydrochloride on the development of the embryo at doses up to 10 mg/day. There was no effect on the development of the embryo at doses up to 10 mg/day. The effects of oral cetirizine hydrochloride on pregnancy outcome or on the health of the child were not evaluated in this study. There is no evidence of any effect of oral cetirizine hydrochloride on the development of the embryo at doses up to 10 mg/day. The effects of oral cetirizine hydrochloride on pregnancy outcome or on the health of the child were not evaluated in this study. There is no evidence of any effect of oral cetirizine hydrochloride on the development of the embryo at doses up to 10 mg/day.
**INDICATIONS AND USAGE**

The recommended dosage is 10 mg administered by intravenous injection. However, in clinical trials with QUZYTTIR and cetirizine hydrochloride tablets, the incidence of adverse reactions reported in children 6 to 11 years of age was similar to that observed in adults.

**SIDE EFFECTS**

No significant sedation has been reported in children treated with cetirizine hydrochloride. The sedation studies were based on in vitro receptor binding studies and in vivo and ex vivo animal models have shown negligible anticholinergic and antihistaminic activity. In clinical studies, the sedation that was observed with cetirizine hydrochloride was similar to that observed with placebo. No adverse effects on growth, development, or behavior were reported in children given cetirizine hydrochloride.

**8 USE IN SPECIFIC POPULATIONS**

**Pediatric Use**

In clinical trials, children 6 to 11 years of age have been treated with cetirizine hydrochloride. The incidence of adverse reactions reported in children 6 to 11 years of age was similar to that observed in adults.

**CONTRIBUTING FACTORS**

The use of QUZYTTIR in combination with a patient’s known highly or moderately dialyzable agent has been concomitantly ingested.

**NURSING AND PRECAUTIONS**

**Side Effects**

The safety and efficacy of QUZYTTIR have been established in patients 18 years of age and older. No significant adverse effects on growth, development, or behavior have been reported in children given cetirizine hydrochloride.

**Infectious Disease**

If the dose administered is less than 10 mg, patients who received cetirizine hydrochloride at 5 mg doses did not require further treatment. In the clinical trial with IV cetirizine hydrochloride in adults, no significant adverse effects on growth, development, or behavior were reported in children given cetirizine hydrochloride.

**Clinical Pharmacology**

In a single dose crossover study in healthy volunteers under fasting conditions, the mean Cmax of cetirizine hydrochloride in adults was found to be 1318 ng·hr/mL and 2746 ng·hr/mL, respectively. The AUC0-inf for cetirizine hydrochloride in adults was 642.1 and 684.2 ng·hr/mL, respectively. The AUC0-inf for cetirizine hydrochloride in pediatric patients was 1018 ng·hr/mL and 2026 ng·hr/mL, respectively. The Cmax of cetirizine hydrochloride in pediatric patients was 1318 ng·hr/mL and 2746 ng·hr/mL, respectively.
| 2 | 3 | 4 |

**FULL PRESCRIBING INFORMATION**

**1 INSTRUCTIONS AND USAGE**

**1.1 Indications and Usage**

**1.1.1 Use**

QUZYTTIR™ is indicated for the treatment of acute urticaria in adults and children 6 months and older.

**1.1.2 Contraindications**

QUZYTTIR is contraindicated in patients with known hypersensitivity to cetirizine hydrochloride, its excipients, benzalkonium chloride, or its preservatives. Use in patients who are receiving concurrent medications that contain levocabastine, terfenadine, astemizole, or any of their metabolites is contraindicated.

**2 DOSAGE AND ADMINISTRATION**

**2.1 Adult Dosage**

The recommended dosage is 10 mg administered by intravenous injection. This dosage should be administered over a period of 1 minute. Cetirizine hydrochloride can be administered at a dose of up to 10 mg/kg/day in children 6 months to 17 years of age. The safety and efficacy of cetirizine hydrochloride at doses higher than 10 mg have not been studied in children less than 12 years of age.

**2.2 Pediatric Dosage**

Cetirizine hydrochloride injection is not recommended for use in infants younger than 1 year of age.

**3 ADVERSE REACTIONS**

**3.1 Overview**

The adverse reactions with QUZYTTIR occurred at an incidence of less than 10% and included drowsiness, headache, epigastric discomfort, constipation, diarrhea, and nasopharyngitis. In pediatric patients (6 months to 17 years of age) treated with cetirizine hydrochloride, the most common reactions observed were fatigue, somnolence, and headache. These reactions are most likely caused by the dosage and duration of treatment and are related to the antihistaminic effects of cetirizine hydrochloride. In adults, the most common adverse reactions observed in clinical trials were tiredness, somnolence, somnolence/alertness, headache, and nasopharyngitis.

**3.2 Overdose**

If overdose with QUZYTTIR occurs, treatment should be symptomatic or supportive. In adults, the symptoms of overdose may include sedation, drowsiness, or dizziness. In children, the symptoms may include drowsiness, somnolence, or agitation. In overdose cases, there is likely to be a decrease in plasma concentrations of cetirizine, and the effects of cetirizine hydrochloride may be lessened. In severe cases, respiratory depression, hypotension, and cardiovascular collapse may occur. The effects of cetirizine hydrochloride may be lessened by supportive care and supportive measures. In severe cases, respiratory depression, hypotension, and cardiovascular collapse may occur. The effects of cetirizine hydrochloride may be lessened by supportive care and supportive measures. In severe cases, respiratory depression, hypotension, and cardiovascular collapse may occur. The effects of cetirizine hydrochloride may be lessened by supportive care and supportive measures. 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abnormalities. See full prescribing information for QUZYTTIR™.

Potentially dangerous effects

Instruct patients to avoid use of alcohol or other CNS depressants, operate dangerous machinery, or engage in any activity requiring alertness, skills, or physical dexterity until it is known how QUZYTTIR affects them. See full prescribing information for QUZYTTIR™.

Contraindications

The safety and efficacy of QUZYTTIR for the treatment of acute urticaria were not altered in patients with abnormal liver function. See full prescribing information for QUZYTTIR™.

Children 6 to 11 years of age

Patients with Hepatic Impairment:

No race-related difference in the kinetics of cetirizine has been observed. See full prescribing information for QUZYTTIR™.

Excretion

In 16 healthy subjects, the mean plasma protein binding of cetirizine is 93%, independent of dose, age, sex, race, or body weight. See full prescribing information for QUZYTTIR™.

Pediatric Patients:

The majority of the patients were Caucasian (48%) and female (63%) with a mean age of 50 years. See full prescribing information for QUZYTTIR™.

The peak plasma levels observed were 250 ng/mL, respectively. Two key secondary efficacy outcome measures: (i) the need to return to any ED or clinic after patient discharge, and (ii) time spent at the treatment center (time from treatment administration to recovery) were compared between treatment groups. The treatment difference and 95% CI were obtained from a generalized linear mixed-effects model. The model consisted of the change from baseline at 2 hours as the dependent variable and site, treatment and site-by-treatment interaction as the fixed effect. The time spent at the treatment center (hours spent reported as mean (SD)) was shorter in the treatment group (2.1 (1.1)) compared to the diphenhydramine treatment group (14%), and the time spent in the treatment center (hours spent reported as mean (SD)) was longer in the treatment group (10.3 (10.2)) compared to the diphenhydramine treatment group (6.2%).

The primary efficacy endpoint was the change in baseline to patient pain visual analog score from 2 to 6 hours for the intent-to-treat (ITT) population. Results were examined on a severity score of 0 to 100 (i.e., 0 = mild, 100 = severe), and a 4-hour area under the curve. The final analysis compared, within the study group, the mean (SD) of change from baseline to pain at the treatment center to the mean (SD) of change from baseline to pain at the treatment center at the second time point (2 hours after the first time point).

The trial was non-inferiority with the pre-specified non-inferiority margin of 0.50 for the difference of diphenhydramine minus QUZYTTIR did not include – 0.50. The inferiority margin, i.e. the lower bound of the 95% confidence interval for the treatment difference, was – 0.50. The majority of the patients were Caucasian (48%) and female (63%) with a mean age of 50 years. See full prescribing information for QUZYTTIR™.
Based on cross-study comparisons, the weight-normalized, apparent absorption with a time to maximum concentration (Tmax) of approximately 1 hour (cetirizine hydrochloride injection) was 390 ng/mL. Based on cross-study comparisons, the apparent total body clearance was 81 to 111% greater and the apparent elimination half-life was 33 to 41% shorter in this pediatric population than in adults. In pediatric patients aged 6 to 23 months who received a single, 5-mg oral cetirizine hydrochloride capsule, the mean Cmax was 275 ng/mL. When pediatric patients aged 7 to 12 years received a 10-mg cetirizine hydrochloride tablet (cetirizine hydrochloride injection), the mean Cmax was 390 ng/mL. The kinetics of cetirizine were studied in 16 healthy subjects. The half-life of cetirizine was studied in 16 healthy subjects. The half-life of cetirizine was estimated to be 3.7 hours, and the apparent total body clearance was 81 to 111% greater and the apparent elimination half-life was 33 to 41% shorter in this pediatric population than in adults.

The majority of the patients were Caucasian (48%) and female (63%) with a mean age of 39 years. The most common adverse reactions in adults included somnolence, fatigue, dry mouth, nausea, headache, and pruritus.

The primary efficacy endpoint was the change from baseline in patient-rated pruritus score assessed 21 post treatment for the intent-to-treat (ITT) population. Pruritus was graded on a severity score of 0 to 3 with 0 = no pruritus, 1 = mild, 2 = moderate, and 3 = severe. A non-inferiority design with the pre-specified non-inferiority margin of 40% was used to determine the difference between treatment groups. The primary key efficacy measures included the proportion of patients with a change of at least 1 point in the patient-rated pruritus score and the mean change from baseline in the patient-rated pruritus score. The non-inferiority margin was set at 20% in 2016 and 40% in 2020 when the time spent at the treatment center from treatment administration to readmission was less than 1 hour. The data from the 2016 and 2020 trials were combined.

The results for the change from baseline in the pruritus score are shown in Table 1. In this trial, approximately 35% of the patients were at risk for the upper respiratory tract infection (URTI) as defined by the change from baseline in the patient-rated pruritus score being at least 1 point. The primary efficacy data are presented in Table 1.

Table 1. Primary Efficacy Endpoint: Patient-rated Pruritus Score Change from Baseline at 2 hours (Postdose) (ITT population)

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In this trial, the proportion of patients receiving 10 mg of QUZYTTIR was 85% lower in the QUZYTTIR treatment group (9% vs. 8% of patients received treatment with one or more additional treatments).

The safety and efficacy of QUZYTTIR for the treatment of acute urticaria was evaluated in a randomized, blinded, placebo-controlled, double-blind, single-dose, flexible-dose study in adult subjects aged 18 to 75 years with acute urticaria. The study was double-blind and placebo-controlled, with up to 60 participants per arm. The study included up to 60 participants per arm. The study included up to 60 participants per arm. The majority of the patients were Caucasian (74%) and female (67%) with a mean age of 39 years. The most common adverse reactions in adults included somnolence, fatigue, dry mouth, nausea, headache, and pruritus.

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<th>Change from Baseline</th>
<th>Mean Change from Baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>QUZYTTIR™</td>
<td>-1.8</td>
<td>-0.9</td>
</tr>
<tr>
<td>Diphenhydramine</td>
<td>-2.0</td>
<td>-1.1</td>
</tr>
</tbody>
</table>

In this trial, the proportion of patients receiving 10 mg of QUZYTTIR was 85% lower in the QUZYTTIR treatment group (9% vs. 8% of patients received treatment with one or more additional treatments).

The safety and efficacy of QUZYTTIR for the treatment of acute urticaria was evaluated in a randomized, blinded, placebo-controlled, double-blind, single-dose, flexible-dose study in adult subjects aged 18 to 75 years with acute urticaria. The study was double-blind and placebo-controlled, with up to 60 participants per arm. The study included up to 60 participants per arm. The majority of the patients were Caucasian (74%) and female (67%) with a mean age of 39 years. The most common adverse reactions in adults included somnolence, fatigue, dry mouth, nausea, headache, and pruritus.

The primary efficacy endpoint was the change from baseline to patient-rated pruritus score assessed 21 post treatment for the intent-to-treat (ITT) population. Pruritus was graded on a severity score of 0 to 3 with 0 = no pruritus, 1 = mild, 2 = moderate, and 3 = severe. A non-inferiority design with the pre-specified non-inferiority margin of 40% was used to determine the difference between treatment groups. The primary key efficacy measures included the proportion of patients with a change of at least 1 point in the patient-rated pruritus score and the mean change from baseline in the patient-rated pruritus score. The non-inferiority margin was set at 20% in 2016 and 40% in 2020 when the time spent at the treatment center from treatment administration to readmission was less than 1 hour. The data from the 2016 and 2020 trials were combined.

The results for the change from baseline in the pruritus score are shown in Table 1. In this trial, approximately 35% of the patients were at risk for the upper respiratory tract infection (URTI) as defined by the change from baseline in the patient-rated pruritus score being at least 1 point. The primary efficacy data are presented in Table 1.

Table 1. Primary Efficacy Endpoint: Patient-rated Pruritus Score Change from Baseline at 2 hours (Postdose) (ITT population)

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